IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAs) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
THIS DOCUMENT RELATES TO:	:	**MDL No. 3094**
ALL ACTIONS / ALL CASES	:	**2:24-md-03094-KSM**

DEFENDANTS' JOINT RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO PERMIT MARKETING DISCOVERY OR TO RECONSIDER ORDER PRECLUDING MARKETING DISCOVERY

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INTRODUCTION

This Court should reaffirm the bifurcated procedure established in Case Management Order (CMO) 18 and deny Plaintiffs' motion for reconsideration seeking to front-load "marketing" discovery. Plaintiffs do not come close to meeting the exacting standard for reconsideration. And permitting marketing discovery at this stage would undercut the efficiencies gained by first handling early discovery and motion practice on cross-cutting issues relating to preemption, adequacy of warnings, and general causation.

Plaintiffs' reconsideration motion is based on the incorrect premise that the Court unilaterally decided the marketing issue with minimal argument from the parties. This Court heard arguments on this issue, weighed them, and resolved the parties' competing positions. Plaintiffs cite no new evidence, no change in the law, and no other ground for reconsideration.

Instead, Plaintiffs repeat the same arguments they made before, contending that marketing discovery may be relevant, in some instances, to whether "the company failed to provide an adequate warning," and that federal preemption might not apply to marketing statements or promotions that depart from the FDA-approved label. But as this Court previously recognized, the adequacy of the warning is a legal issue that turns on the content of the label's warnings. Preemption likewise is a legal issue that can be resolved in Defendants' favor when the record shows (1) Defendants did not have newly acquired information showing a causal association, or (2) clear evidence that FDA would have rejected the proposed warning. *See* Doc. No. 235 (CMO 18), at 8 ("[T]he Court does not need to consider each Plaintiff's specific circumstances to determine: (1) whether the Court can rule as a matter of law that Defendants' labels adequately warn for the gastrointestinal symptoms and events common to all Plaintiffs (i.e., label adequacy), and (2) whether Defendants should have (or could have) revised their labels to provide additional warnings which Plaintiffs argue were required as a matter of state law (i.e., preemption).").

Resolution of these cross-cutting issues, as the Court found, "could limit many of the claims in this MDL, or at minimum, hone the parties' arguments as they relate to Defendants' failure to warn." *Id.* at 9. And there is no dispute that Plaintiffs will have access to the information they need to litigate those cross-cutting issues. Indeed, the Court has already permitted, and Lilly and Novo have agreed to produce, medical, scientific, and regulatory discovery. Marketing evidence is not relevant to either question.

In their motion for reconsideration, Plaintiffs seek broad-ranging and burdensome marketing discovery to pursue litigation angles peripheral to these core, cross-cutting issues, raise theoretical scenarios not pleaded in their filed failure-to-warn claims, and pose case-specific questions about the application of the learned intermediary doctrine or warnings causation to individual prescribing physicians. This Court correctly found that such questions would be most efficiently addressed in a subsequent stage of this MDL, if necessary, after the prioritized issues have been resolved. The Court should deny Plaintiffs' motion.

BACKGROUND

For the past few months, the Court has been working with the parties to determine how most efficiently to structure this litigation in light of Plaintiffs' counsel's representation that they intend to file at least 10,000 cases and Defendants' view that many (if not all) of these cases are not viable as a matter of law for multiple reasons. Plaintiffs had full notice of which cross-cutting issues might be prioritized, and Plaintiffs responded by arguing no fewer than five times that they should receive early access to wide-ranging marketing-related discovery. *See* Doc. No. 87, at 1 (Plaintiffs' Position Statement); Doc. No. 175, at 12 (July 3 brief); July 10 Hr'g Tr. 99:8-21; July 26 Hr'g Tr. 8:18-11:23; Aug. 2 Hr'g Tr. 9:16-24. Plaintiffs repeatedly argued that marketing discovery might be relevant to Plaintiffs' subjective beliefs about potential side effects. *See* July 26 Hr'g Tr. 10:23-11:23. Plaintiffs, however, failed to connect their broad assertions about

marketing to the prioritized cross-cutting issues, which this Court recognized by postponing marketing discovery until later stages of litigation. CMO 18, at 10 n.9.

As this Court noted in CMO 18, many MDL courts have "found it effective to prioritize discovery and motion practice on specific issues as a means to efficiently manage and streamline pretrial proceedings." *Id.* at 2 n.3. The Court found such efficiencies will be gained by first addressing Gastroparesis Diagnostic Testing (Issue 1) and Preemption and Adequacy of the Warning Labels (Issue 2). The Court is considering whether General Causation (Issue 3) is also a cross-cutting issue amenable to early consideration. Prioritizing these cross-cutting issues will streamline the litigation because they could "limit many of the claims in this MDL or at minimum, hone the parties' arguments as they relate to Defendants' alleged failure to warn." *Id.* at 9. The Court recognized that it need not resolve *all* specific claims or evaluate each Plaintiff's circumstances to gain substantial efficiencies. *See id.*

LEGAL STANDARD

"Before altering or amending a prior decision, courts in this Circuit require the moving party to show one of three bases: '(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.'" *Trainer v. Cnty. of Del.*, No. 23-CV-1940, 2024 WL 3070179, at *1 (E.D. Pa. June 18, 2024) (Marston, J.) (quoting *Max's Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999) (alteration omitted)). "A motion for reconsideration may not be used to give a litigant a 'second bite at the apple,' and therefore should not be 'grounded on a request that a court rethink a decision already made.'" *Jarzyna v. Home Props., L.P.*, 185 F. Supp. 3d 612, 622 (E.D. Pa. 2016), *aff'd*, 783 F. App'x 223 (3d Cir. 2019) (quoting *Bhatnagar v. Surrendra Overseas Ltd.*, 52 F.3d 1220, 1231 (3d Cir. 1995), and *In re Blood Reagents Antitrust Litig.*, 756 F. Supp. 2d 637, 639 (E.D. Pa. 2010)).

ARGUMENT

I. Plaintiffs Have Not Met the Standard for Reconsideration.

Plaintiffs do not cite, much less attempt to meet, the standard for reconsideration. Reversing a prior order is an extraordinary action that should only be taken when warranted by a unique circumstance. "The purpose of a motion for reconsideration is to correct manifest errors of law or to present newly discovered evidence. Out of consideration for finality and judicial economy, courts should grant motions for reconsideration sparingly." *Trainer*, 2024 WL 3070179, at *1 (internal quotation marks and citations omitted). Plaintiffs admittedly do not rely on any change in the law, any new evidence, or any clear error by the Court. Instead, they recycle arguments they have already made about claims they have not pled.

Plaintiffs argue the Court's decision came without adequate argument from the parties or consideration by the Court. Mot. for Reconsideration 1 & n.1. Thus, their "position is that the Court should view the instant motion not as a reconsideration but as the first full hearing on this matter." *Id.* at 4. Plaintiffs' position is demonstrably incorrect. Plaintiffs already made these exact same arguments (repeatedly) in briefing and oral argument to the Court and the motion for reconsideration simply repackages arguments made repeatedly during court conferences and in prior briefs.[1]

Accordingly, the Court should reject Plaintiffs' motion on the ground that it seeks to relitigate this Court's discretionary decision after Plaintiffs' ample opportunity to raise their request for early marketing discovery.

[1] Plaintiffs claim that reconsideration is consonant with justice. Mot. for Reconsideration 4. However, even under that standard, parties may not use reconsideration as a second bite at the apple. *Jarzyna*, 185 F. Supp. 3d at 622.

II. The Court Correctly Ruled That Marketing Discovery Is Not Necessary for the Cross-Cutting Issues.

The Court has prioritized the threshold questions whether the FDA-approved product labeling was adequate as a matter of law and whether federal law permitted the manufacturers to unilaterally change the labeling. It is also considering whether to front-load general causation. This prioritization recognizes that the FDA-approved warning labels are the bedrock of failure-to-warn claims. Plaintiffs do not now challenge the Court's decision to start with these cross-cutting issues. Rather, they seek to undermine the practical value and inherent efficiencies of the bifurcated procedure by demanding immediate marketing-related discovery.

The Court, however, was correct, that marketing discovery should wait until the initial cross-cutting issues are decided because it is not relevant to the front-loaded issues as framed by the Court and because resolution of the cross-cutting issues may obviate or substantially narrow the scope of any marketing discovery eventually required. *See* CMO 18, at 10 n.9. The Court further observed it can determine as a matter of law whether "the Defendants' *labels* adequately warn for gastrointestinal symptoms and events common to all Plaintiffs," or whether Defendants could have revised their labels. *Id.* at 8. Marketing evidence does not bear on the adequacy of the label itself or whether the manufacturer could change the label—issues that are essential to the failure-to-warn claim that Plaintiffs have made the centerpiece of this MDL. Plaintiffs do not argue otherwise. To the extent claims survive the first analysis, this Court appropriately left open whether or how eventual rulings on these cross-cutting issues may apply to the circumstances of each specific Plaintiff, the learned intermediary doctrine, or given the vagaries of a particular state law. At that future stage, the Court and parties will better know the degree, scope, and relevance of any potentially discoverable marketing evidence. That is an efficient and appropriate way to proceed, and one followed by the many MDL courts cited in CMO 18. *Id.* at 2 n.3.

To second-guess this determination, Plaintiffs raise a laundry list of potential ways in which marketing evidence might theoretically apply in some unspecified case; but not this case at this stage. Plaintiffs' arguments stray far afield from any allegations actually pleaded in the filed complaints and are entirely disconnected from the specific injuries—gastroparesis and gastrointestinal symptoms—that are the primary focus of this MDL. Plaintiffs' motion only underscores how marketing discovery does not advance the prioritized, cross-cutting issues. Instead, such broad-ranging discovery would burden and distract the Court and the parties from efficiently resolving the cross-cutting issues at hand.

A. Marketing Discovery Is Not Needed to Resolve Threshold Warning-Adequacy Issues.

As to adequacy of the warning, Plaintiffs argue that marketing evidence should be propounded now because "overpromotion" can "dilute" or "nullify" a warning. Mot. for Reconsideration 7-11. However, Plaintiffs' complaints have at their core an assertion that Defendants failed to warn of specific risks (primarily gastroparesis) on their FDA-approved labels. The first and primary question for a prescription medication is the adequacy of the *labeled* warning. Plaintiffs' argument is that, *even if the labeled warnings are adequate*, company marketing could theoretically (and under potentially a handful of state laws) dilute the labeled warning.

At the outset, these theories do not align with the claims that are on file. In this MDL, Plaintiffs' complaints focus on the warning label itself and do not point to any specific marketing messages inconsistent with the FDA-approved labels, which warned of gastrointestinal and other specific injuries. *See, e.g.*, *Craig v. Novo Nordisk Inc.*, No. 24-CV-1075, Compl. ¶ 231. The filed pleadings also do not allege that the physician of any particular Plaintiff relied on marketing representations rather than the labeling to make a prescribing decision.

Meanwhile, the caselaw Plaintiffs cite demonstrates that few, if any, states presently

recognize an "overpromotion" exception to the learned intermediary doctrine. Indeed, in *In re Avandia*, which Plaintiffs cite at length, Judge Rufe noted she found only *one* Pennsylvania case from 1971 recognizing this theory and could find no other state that adopted a so-called "overpromotion" exception. 817 F. Supp. 2d 535, 555 n.108 (E.D. Pa. 2011).[2] Notably, moreover, the plaintiffs in *Avandia* did not invoke generalized marketing campaigns; instead, they argued that evidence showed the defendant "diluted the effect" of the labeled warning by engaging in specific "efforts to disassociate" the risk of a particular adverse event from the medication. *Id.* at 555. Likewise, the cases cited by Plaintiffs at pages 8 to 9 of their Motion relate to evidence in specific cases that caused an individual prescribing physician to disregard the labeled warning. These types of arguments, at best, reduce down to matters of particular state law, and fact-specific circumstances that could be addressed in the show-cause process or in the next stage of this litigation, as this Court previously and correctly held.

B. Marketing Discovery Is Not Needed to Resolve Threshold Preemption Issues.

Plaintiffs' Motion concedes that marketing evidence is irrelevant to whether federal law permitted Defendants to unilaterally modify the labeled warnings under the Changes Being Effected regulation, which requires a manufacturer to possess newly acquired information showing a causal association between the product and an adverse event. 21 C.F.R. § 314.70(c)(6)(iii). Nor does marketing evidence bear on whether FDA action otherwise foreclosed a label change.

[2] Plaintiffs similarly mischaracterize the statement in *In re Testosterone Replacement Therapy Products Liability Litigation* regarding the extent to which any other states recognize an "overpromotion" theory. No. 14 C 1748, 2017 WL 1836435 (N.D. Ill. May 8, 2017). The cited portion of that case states that promotional activity may overcome the rebuttable *presumption* of adequacy for the FDA-approved label applied by Tennessee and Utah law (one that is also employed in several other states). *Id.* at *16. The Court further noted its prior rulings that showed a *case specific* dispute whether the particular "physicians for each of these plaintiffs was impacted" by promotion of the medicine in a way that "caused the prescribing doctor to disregard the *otherwise adequate warnings*." *Id.* at *17 (emphasis added).

Instead, Plaintiffs make an unremarkable observation that "no federal law requires Defendants to make verbal or written communications with doctors or the medical community that are inconsistent with the label." Mot. for Reconsideration 12. But neither Plaintiffs' pleadings, nor even their Motion for Reconsideration, cite any such verbal or written communications that deviate from the FDA approved label, much less in ways relevant to gastroparesis.[3] It is unsurprising, therefore, that Plaintiffs' filed complaints do not identify any particular prescribing physician who relied on advertisements or other non-labeled statements inconsistent with the FDA approved labeling. And even if they did, that case-specific issue involves a narrow (and potentially null) set of cases and is plainly secondary to the threshold question of whether the label itself could have been modified to include a gastroparesis or other claimed warning.[4]

Plaintiffs also claim that preemption does not apply to off-label marketing. Mot. for Reconsideration 3-4. But this case is not about off-label promotion. Plaintiffs make no claim that the risk of gastroparesis (if it exists at all) bears any relation to whether the prescription fell within

[3] Notwithstanding the many paragraphs of each complaint devoted to generalized allegations about how these medications are marketed, none of the allegations have relevance to gastroparesis. Instead, these sections of the complaints make allegations about the companies' overall volume and expenditure on marketing activities, Novo Nordisk's non-branded efforts to raise awareness of obesity as a chronic disease, or third parties' recognition of these medications in social media and other fora. *See, e.g.*, *Miller v. Novo Nordisk*, No. 23-CV-3924, Compl. ¶¶ 58-168.

[4] The cases Plaintiffs cite (Mot. for Reconsideration 12) to claim marketing's relevance to preemption are entirely distinguishable. *See, e.g.*, *In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 11-MD-2299, 2014 WL 12776173, at *13, *17-18 (W.D. La. Sept. 5, 2014) (rejecting post-trial preemption argument where evidence at trial supported the jury's finding that bladder cancer was a known, unwarned-of risk); *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, No. 05-1699 CRB, 2006 WL 2374742, at *11 (N.D. Cal. Aug. 16, 2006) (finding that manufacturer's submission of advertisements to FDA did not necessarily render all state law claims related to those advertisements preempted by federal law and declining to rule that advertisements were not misleading as a matter of law because of the "limited record and briefing"); *City & Cnty. of S.F. v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 666 (N.D. Cal. 2020) (in governmental nuisance and consumer protection suit, evaluating manufacturer's statements that diverged from the label warnings).

the indicated uses or populations. While Plaintiffs' complaints make generic assertions of "off label" promotion, they do not connect these allegations to their own prescribing physicians or their own claimed injuries.[5]

In arguing otherwise, Plaintiffs again misplace reliance on a decision in the *In re Testosterone Replacement Therapy* MDL. Mot. for Reconsideration 12. In that case, the court did not find an off-label exception to impossibility preemption where a manufacturer was otherwise prohibited from changing an FDA-approved label. Instead, the Court considered whether the plaintiffs' claims "constitute[d] an improper attempt to privately enforce FDA regulations that prohibit drug manufacturers from promoting off-label uses of their drugs." *See In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2017 WL 1836443, at *7 (N.D. Ill. May 8, 2017). It held that the plaintiffs' claims of fraud and misrepresentation based on alleged off-label marketing did "not depend on a finding that [the manufacturer] violated the FDCA" by engaging in off-label promotion, and therefore did not trigger implied preemption arising out the FDCA's provision prohibiting private enforcement, 21 U.S.C. § 337(a), and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 344 (2001). *See In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2017 WL 1836443, at *6-8 (N.D. Ill. May 8, 2017). Plaintiffs are even further afield in their reliance on *Lempa v. Eon Labs, Inc.,* No. 18 C 3821, 2019 WL 1426011, at *4 (N.D. Ill. Mar. 29, 2019), and *Ramirez v. Medtronic*, 961 F. Supp. 2d 977 (D. Ariz. 2013). The defendant in *Lempa* was a generic manufacturer that argued all claims against it

[5] Meanwhile, Defendants have pointed to their own proactive steps to encourage physicians to prescribe these medications consistent with their FDA-approved indications. Novo Nordisk, *Perspectives from Novo Nordisk* (May 2023), *available at* https://www.novomedlink.com/content/dam/novomedlink/semaglutide/Responsible-Use-Letter.pdf; Lilly, *An Open Letter from Eli Lilly and Company Regarding Certain Practices Related to Mounjaro and Zepbound* (June 20, 2024), *available at* https://investor.lilly.com/node/50961/pdf.

were preempted because generic warning labels must mirror the relevant brand label; the court found that off-label marketing likely took the generic product outside of those preemption protections. 2019 WL 1426011, at *4. *Ramirez* involved an exception to express, not implied, preemption in a medical device case. 961 F. Supp. 2d at 990.

Finally, Plaintiffs make unfounded assertions that they might find marketing materials that show efforts to hide risks from regulatory authorities. Mot. for Reconsideration 3. But the relevant inquiry is whether the companies had information about the supporting causal association as to alleged injuries that they did not disclose to the FDA, and that would be contained in the discovery that the Court has already ordered.

III. Granting Plaintiffs' Motion Would Undermine the Efficiencies of the Court's Bifurcated Process.

The marketing discovery sought by Plaintiffs is wide ranging and highly burdensome, including exploration of the conduct and communications of individual sales representatives, third-party companies, as well as electronic and hardcopy marketing materials spanning multiple geographies and time periods. Embarking on this massive discovery enterprise at the outset of this MDL will undercut the purpose of prioritizing cross-cutting questions and cause delay while the parties litigate about burdensome, irrelevant discovery. *See* Plaintiffs' First Set of Rqsts. for Prod. Nos. 7, 8, 11-15, 17, and 23; *see also* Plaintiffs' Third Set of Rqsts. for Prod., Nos. 41-50 and 52.

In addition to the marketing discovery demanded from Novo and Lilly, Plaintiffs already have served third-party subpoenas on ConcentricLife, Noom, Roman Health Ventures, and Weight Watchers, fishing for extensive marketing-related productions including communications among dozens of different entities over the last decade, seeking contracts, invoices, employee education, budgets, telehealth platforms, an array of websites, investments, board members, meetings, discount strategies, legal actions related to Novo or Lilly, and Oprah Winfrey's work on GLP-

1RAs. *See, e.g.*, Exhibit A, at 17-18; Exhibit B, at 13-18; Exhibit C, at 13-16; Exhibit D, at 14-17. Plaintiffs offer no explanation why this onerous discovery should be pursued now.

The caselaw relied on by Plaintiffs about the purported relevance of marketing discovery also does not help them—those cases involve very different procedural stages and say nothing about the propriety and efficiency of front-loading discovery relevant to cross-cutting issues. For example, in *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, 369 F.3d 293, 314 (3d Cir. 2004), the Third Circuit reviewed the district court's exclusion of marketing evidence ***at trial***. The court said that, if the defendant-manufacturer had marketed drugs "at the expense of" ensuring they were safe, the trial court's categorical exclusion of that evidence at trial was improper. *Id.* The court also explained the limitations of marketing evidence, which Plaintiffs here omit from their brief: "Evidence tending simply to show that [the manufacturer] wanted to successfully market the diet drugs and make a profit selling them would ***not be relevant*** to show, for example, that [the manufacturer] acted negligently." *Id.* (emphasis added).[6]

This Court appropriately followed the model set by a host of MDL courts across the country[7] to create an efficient structure for prioritizing discovery most relevant to issues that will shape and narrow this litigation.

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[6] Similarly, *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liab. Litig.*, No. 11-MD-2244, 2017 WL 3841608, at *4 (N.D. Tex. June 28, 2017), was a post-trial order denying a new trial where the plaintiff introduced an email about risks posed by a device similar to the one implanted into the plaintiff. *See also In re Depakote*, 87 F. Supp. 3d 916, 928 (S.D. Ill. 2015) (permitting admission of marketing materials at trial to show knowledge of adverse event risk); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & PMF Prods. Liab. Litig.*, No. 09-CV-10012, 2011 WL 6740391, at *10 (S.D. Ill. Dec. 22, 2011) (same).

[7] *In re Zantac (Ranitidine) Prods. Liab. Litig.*, No. 20-MD-2924, Pretrial Order No. 30 (S.D. Fla. June 18, 2020); *In re Viagra (Sildenafil Citrate) Prods. Liab. Litig.*, No. 16-MD-02691, Doc. No. 102 (N.D. Cal. Sept. 26, 2016); *In re Incretin Mimetics Prods. Liab. Litig.*, No. 13-MD-2425, Doc. No. 325 (S.D. Cal. Feb. 18, 2014).

CONCLUSION

For all of these reasons, Defendants respectfully request that the Court deny Plaintiffs' motion for reconsideration.

Dated: September 20, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2024, a true and correct copy of the foregoing Defendants' Joint Response in Opposition to Plaintiffs' Motion to Permit Marketing Discovery or to Reconsider Order Precluding Marketing Discovery was electronically filed using the Court's CM/ECF System, which will send notification of such filing to all counsel of record.

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